DEPARTMENT OF HEALTH & HUMAN SERVICES M1025 N Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-68

June 26, 1997

Richard T. Isel, President
Sterile Recoveries, Inc.
28100 U.S. Hwy. 19 N., Suite #201
Clearwater, Florida 33761

Dear Mr. Isel:

We are writing to you because on June 2 through 11, 1997 FDA Investigator R. Kevin Vogel collected information that revealed serious regulatory problems involving products identified as sterile and non-sterile surgical kits, which are manufactured and marketed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the CGMP. These violations include, but are not limited to the following:

- Failure to validate significant manufacturing processes, e.g., to complete packaging seal integrity validation using a statistically relevant number of samples to demonstrate validation is complete and specifications will be consistently met.

- Failure to establish adequate complaint handling procedures required to review, evaluate, and investigate complaints, e.g., failure to analyze all sources of quality data to identify existing and potential causes of nonconforming product; ensure that corrective actions are documented, verified, and if necessary, validated to correct identified problem; and failure to assure action needed to correct seal failures reported in four complaints.

- Failure to verify and/or validate all sterilization processes, e.g., failure to assure [redacted] sutures are not adversely affected by EtO sterilization cycle; failure to perform bioburden studies; failure to conduct EtO residue testing on susceptible components; and failure to assure biological indicators meet specifications.

- Failure to verify incoming components to assure they meet specifications, e.g., examine surgeon's gloves are free of defects and electrosurgical pencils operate as intended.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite #120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for conformance of your devices with the GMPs and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about the GMP requirements and how they affect your particular device, or about the content of this letter, please contact Tim Couzins at (407) 6486823, ext. #264.

Sincerely yours,

Douglas D. Tolen
Director, Florida District